

Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Test Article: NB101
Study Number: 1300972-S01
Study Received Date: 19 May 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0145 Rev 05
Deviation(s): None

Summary: This procedure was performed to evaluate the differential pressure of the sponsor supplied product. The air exchange differential or breathability was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003 (with the exception that the product was not a respirator). The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Test Article Number	Inhalation Resistance (mm H ₂ O)	Exhalation Resistance (mm H ₂ O)
1	4.1	1.6
2	4.3	1.4
3	4.4	2.2

Test Method Acceptance Criteria: The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.



Brent Shelley electronically approved for
Study Director

Curtis Gerow

11 Jun 2020 15:24 (+00:00)

Study Completion Date and Time

Procedure: A product was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).